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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,603	03/16/2006	Peter H. Breen		7178
33197	7590	07/09/2008	EXAMINER	
STOUT, UXA, BUYAN & MULLINS LLP			PATEL, NIHIL B	
4 VENTURE, SUITE 300			ART UNIT	PAPER NUMBER
IRVINE, CA 92618			3772	
MAIL DATE		DELIVERY MODE		
07/09/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,603	Applicant(s) BREEN, PETER H.
	Examiner NIHIR PATEL	Art Unit 3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on **04.11.2008**.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) **1-22** is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) **1-22** is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

Response to Amendment

2. The examiner acknowledges the amendment filed on April 11th, 2008. The amendment comprises amending claims 1 and 16. No claims have been cancelled or added.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1-3, 6, 10-15** are rejected under 35 U.S.C. 102(b) as being anticipated by Elam (US 3,898,987).

5. **As to claim 1**, Elam teaches an apparatus that comprises an inspiratory flow conduit **16** (**see figure 1; col. 1 lines 50-55**) for delivering a flow of inspiratory gas to the lungs of the patient; an expiratory flow conduit **18** (**see figure 1; col. 1 lines 50-55**) for carrying expired gas from the lungs of the patient; a ventilation apparatus **23** (**see figure 1**) attached to the inspiratory flow conduit for moving inspiratory gas through the inspiratory flow conduit toward the lungs of the patient; and a spirometric device **25** (**see figure 1; col. 1 lines 60-65**) comprising a chamber **38** (**see figure 1; col. 2 lines 65-67**) within which a volume of oxygen is contained and an indicator **28** (**see figure 1; col. 3 lines 15-25**) for indicating changes in the volume of oxygen

contained within the chamber; the spirometric device being connected to the expiratory flow conduit such that the volume of oxygen contained in the chamber will decrease by a volume that is equivalent to the volume of oxygen taken up by the patient (**see figure 1; col. 3 lines 15-40**).

6. **As to claim 2**, Elam teaches an apparatus that further comprises a carbon dioxide absorber **21** connected to the system such that gas from the expiratory flow conduit will pass through the carbon dioxide absorber where carbon dioxide will be removed from the gas and the gas will subsequently flow from the carbon dioxide absorber into the inspiratory flow conduit (**see col. 1 lines 50-60**).

7. **As to claim 3**, Elam teaches an apparatus that further comprises a valve **54** positioned between the spirometry device and the expiratory flow conduit, the valve being open only during a late portion of the expiratory phase of the ventilation cycle, thereby preventing substantial pressure variations within the spirometric device as a result of inhalation and exhalation (**see col. 2 lines 39-45**).

8. **As to claim 6**, Elam teaches an apparatus that comprises a source **20** of make up oxygen connected to the ventilation circuit (**see figure 1; col. 1 lines 50-60**).

9. **As to claims 10 and 11**, Elam teaches an apparatus wherein the spirometric device comprises a water/dry sealed spirometer (**see col. 1 lines 15-30**)

10. **As to claim 12**, Elam teaches an apparatus wherein the chamber moves in relation to the volume of oxygen contained within the chamber and wherein the indicator comprises an indicator of chamber movement (**see figure 1; col. 3 lines 15-25**).

11. **As to claim 13**, Elam teaches an apparatus wherein the indicator comprises a scale **58** marked on the chamber **38** to indicate the distance by which the chamber has moved (**see figure 1; col. 5 lines 5-15**).

12. **As to claim 14**, Elam teaches an apparatus wherein the ventilation apparatus comprises a bag **48**, ventilator, bellows or other manual or automatic ventilating apparatus (**see figure 1; col. 2 lines 60-65**).

13. **As to claim 15**, Elam teaches an apparatus wherein the ventilating apparatus returns to the same volume prior to each breath (**see col. 3 lines 15-25**).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims **4, 5 and 7-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Elam (US 3,898,987) in view of Philips et al. (US 3,789,837).

17. **As to claim 4**, Elam substnatially discloses the claimed invention; see rejection of claims 1 and 3 above, but does not disclose a control device which sends signals to the valve to cause the valve to open and close a predetermined points on the ventilation cycle. Philips discloses an apparatus that does disclose disclose a control device which sends signals to the valve to cause the valve to open and close a predetermined points on the ventilation cycle (**see col. 10 lines 15-25**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Elam's invention by providing a control device which sends signals to the valve to cause the valve to open and close a predetermined points on the ventilation cycle as taught by Philips in order to prevent the user from inhaling contaminated gas.

18. **As to claim 5**, Elam substnatially discloses the claimed invention; see rejection of claims 1, 3 and 4 above, but does not disclose a controller that is operative to cause the valve to open at approximately the end of each expiration and to close at approximately beginning of each inspiration. Philips discloses an apparatus that does provide a controller that is operative to cause the valve to open at approximately the end of each expiration and to close at approximately beginning of each inspiration (**see col. 10 lines 15-25**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Elam's invention by providing a controller that is operative to cause the valve to open at approximately the end of each expiration and to close at approximately beginning of each inspiration as taught by Philips in order to prevent the user from inhaling contaminated gas.

19. **As to claim 7**, Elam substnatially discloses the claimed invention; see rejection of claims 1 and 6 above, but does not disclose a flow control apparatus for controlling the flow of make up oxygen into the ventilation circuit. Philips discloses an apparatus that does provide a flow control

apparatus for controlling the flow of make up oxygen into the ventilation circuit (**see col. 3 lines 15-25**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Elam's invention by providing a flow control apparatus for controlling the flow of make up oxygen into the ventilation circuit as taught by Philips so that the patient/user does not inhale too much oxygen.

20. **As to claim 8**, Elam substantially discloses the claimed invention; see rejection of claims 1, 6 and 7 above, but does not disclose a flow control apparatus that is adapted to increase or decrease the flow of make up oxygen into the ventilation circuit in response to control signals and a control device which sends control signals to the flow control apparatus to increase or decrease the flow rate of make up oxygen into the ventilation circuit. Philips discloses a flow control apparatus that is adapted to increase or decrease the flow of make up oxygen into the ventilation circuit in response to control signals and a control device which sends control signals to the flow control apparatus to increase or decrease the flow rate of make up oxygen into the ventilation circuit (**see col. 3 lines 15-25**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Elam's invention by providing a flow control apparatus that is adapted to increase or decrease the flow of make up oxygen into the ventilation circuit in response to control signals and a control device which sends control signals to the flow control apparatus to increase or decrease the flow rate of make up oxygen into the ventilation circuit as taught by Philip so that the patient/user does not inhale too much oxygen.

21. **As to claim 9**, Elam substantially discloses the claimed invention; see rejection of claims 1, 6, 7 and 8 above, but does not disclose a controller to cause the flow control apparatus to

increase or decrease the flow of make up oxygen as required to prevent more than a predetermined amount of change in the volume of oxygen contained in the cylinder. Philips discloses an apparatus does provide a controller to cause the flow control apparatus to increase or decrease the flow of make up oxygen as required to prevent more than a predetermined amount of change in the volume of oxygen contained in the cylinder (**see col. 3 lines 15-25**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Elam's invention by providing a controller to cause the flow control apparatus to increase or decrease the flow of make up oxygen as required to prevent more than a predetermined amount of change in the volume of oxygen contained in the cylinder as taught by Philips so that the patient/user does not inhale too much oxygen.

22. Claims **16-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Elam (US 3,898,987)

23. **As to claim 16-22**, Elam substantially discloses a method step of providing a closed ventilation circuit that comprises an expiratory flow conduit **18** for carrying expired gas from the lungs of the patient, a ventilation apparatus **23** attached to the inspiratory flow circuit for moving inspiratory gas through the inspiratory flow conduit **16** toward the lungs of the patient and a spirometric device **25** comprising a chamber **38** which contains a volume of oxygen and an indicator **28** for indicating changes in the volume of oxygen contained within the chamber, wherein the spirometric device is connected to the expiratory flow conduit such that the volume of oxygen contained in the chamber of the spiraometric device will vary relative to the volume of oxygen taken up by the patient; connecting the ventilation circuit to the patient such that the patient will inhale and exhale through the ventilation circuit and determining the change in the

volume of oxygen contained in the chamber of the spirometric device as an indication of oxygen uptake by the patient.

The claimed method steps would have been obvious because they would have resulted from the use of the device of Elam.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3772

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772